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APPLICATION NO. FILING DATE		ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,337	08	3/25/2000	KEQIANG WU	104107.01 5854	
25944	7590	07/01/2003			
OLIFF & B	ERRIDGI	E, PLC	EXAMINER		
P.O. BOX 19928 ALEXANDRIA, VA 22320				MEHTA, ASHWIN D	
				ART UNIT	PAPER NUMBER
				1638	25
				DATE MAILED: 07/01/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

	-	Application No.	Applicant(s)				
7	_						
	Office Action Summary	09/645,337	WU ET AL.				
	omoc Addon Gammary	Examiner	Art Unit				
<u> </u>	The MAILING DATE of this communication and	Ashwin Mehta	1638				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1 136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)⊠	Responsive to communication(s) filed on 21 A	<u>pril 2003</u> .					
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 1-3,5-9,11-19,31-49 and 51-53 is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.						
	5) Claim(s) 31 is/are allowed.						
	6) Claim(s) 1-3,5-9,11-19 and 32-41 is/are rejected.						
7) Claim(s) <u>42-49 and 51-53</u> is/are objected to.							
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers							
	The specification is objected to by the Examiner						
10)⊠ The drawing(s) filed on <u>21 April 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
<ul> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)				

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#### **DETAILED ACTION**

- 1. The request filed on 21 April 2003 for continued examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/645,337 is acceptable, and an RCE has been established. An action on the RCE follows.
- 2. The objection to the Figure 4 is withdrawn, in light of the substitute figure submitted 21 April 2003.
- 3. The objection to the specification for failing to comply with 37 CFR 1.821-1.825 is withdrawn, in light of the insertion of sequence identifiers in the brief descriptions of Figures 3 and 4.
- 4. The rejection of claims 9, 11-13, 17-19, and 29 is withdrawn, in light of the claim amendments.
- 5. The rejection of claims 1-3, 5-8, and 14-16 under 35 U.S.C. 103(a) is withdrawn, in light of the claim amendments.

#### **Drawings**

6. Substitute Figures 1A-B, 2A-B, 3-10, 17, 18, 19A-C, and 20-24 have been received. As indicated on the accompanying Office Action Summary, the Examiner does not have any

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objections to these figures. However, Applicants are notified that a Draftsperson was not available to review the figures prior to the mailing of the instant Office action.

## Claim Objections

7. Claims 42-49, and 51-53 are objected to for being dependent on a rejected base claim.

Claims 52 and 53 are objected to under 37 CFR 1.75 (b) as being duplicate claims.

Applicant is required to cancel one of the claims, or amend the claim(s).

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 36 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation, "nucleotides 61-855 of SEQ ID NO: 7; and nucleotides 61-655 of SEQ ID NO: 7" in claim 36, and "a nucleotide sequence that hybridizes to nucleotides 61-855 of SEQ ID NO: 7; and a nucleotide sequence that hybridizes to nucleotides 61-655 of SEQ ID NO: 7" in claim 41, renders the claims indefinite. Parent claim 1 does not mention nucleotides 61-855 and 61-655 of SEQ ID NO: 7. Claims 36 and 41 broaden the scope of the claim from which they depend.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 36 are 41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 17 March 2003 under 5. Applicants traverse the rejection in the paper received 21 April 2003.

Applicants argue that Figure 10 displays several constructs of AtHD2A that were prepared and tested, that Figure 2 indicates the relationships between the amino acid and nucleotide sequences of AtHD2A and AtHD2B, and that the table provided on page 11 of the February 20, 2003 Amendment After Final Rejection lists the corresponding nucleotide and amino acid numbering for SEQ ID NO: 5 (response, paragraph bridging pages 7-8). Applicants argue that nucleotides 49-267 and 457-534 of SEQ ID NO: 5 refer to amino acids 1-73 and 137-163, which are the catalytic residues and the acidic domain of histone deacetylase, and that they are conserved between AtHD2A, AtHD2B, and ZmHD2. Applicants argue that based upon the homology between AtHD2A and AtHD2B in Figures 3 and 4, it can be established that nucleotide positions determined associated in SEQ ID NO: 7 correspond to similar positions as those identified in SEQ ID NO: 5 (response, page 8, 1<sup>st</sup> and 2<sup>nd</sup> full paragraphs). Applicants continue, arguing that the fragment comprising 1-73 of AtHD2A corresponds to amino acids 1-72 of AtHD2B and amino acids 137-163 of AtHD2A corresponds to amino acids 154-198 of AtHD2B (response, paragraph bridging pages 8-9).

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However, as discussed previously, the specification does not mention that the amino acid sequences encoded by nucleotide fragments 61-855 and 61-655 of SEQ ID NO: 7 retain the activity of SEQ ID NO: 8, nor does the specification describe the catalytic residues and acidic domain of AtHD2B. Applicants' argue that the locations of the catalytic residues and acidic domain of AtHD2B can be inferred from the nucleotide and amino acid sequences of AtDH2A. However, AtHD2B has 60 more amino acid residues than AtHD2A. The significance of the additional residues in AtHD2B is not mentioned in the specification. Applicants in their remarks (and not in the specification) indicate that the acidic domain of AtHD2B corresponds to residues 154-198 of SEQ ID NO: 8. However, it is noted that this domain is 18 amino acids larger than the acidic domain of AtHD2A. One skilled in the art would not have inferred this from the specification and drawings as filed. It is maintained that the recitations in the claims directed to nucleotide sequences encoding amino acids 61-855 and 61-655 of SEQ ID NO: 7 is NEW MATTER and must be removed. Applicants have indicated that references to nucleotides 61-655 and 61-855 of SEQ ID NO: 7 were removed from claims 1 and 9. However, the references still appear in dependent claims 36 and 41.

10. Claims 1-3, 5-19, and 32-41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 17 March 2003 under 5. Applicants traverse the rejection in the paper received 21 April 2003.

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Applicants argue that Figures 9, 10, 17-19, and Examples 2 and 3 indicate that the combination of effector and reporter plasmids results in reduced activity of GUS enzyme activity, and that this demonstrates that reduced enzyme activity is regulated in the presence of histone deacetylase (response, paragraph bridging pages 6-7). However, this does not conclusively prove that histone deacetylase affected translation of GUS, or the GUS enzyme itself. From their response, Applicants appear to indicate that histone deacetylase affected the activity of the GUS enzyme itself. However, there is no teaching at all, in the specification or the prior art, that histone deacetylase can affect the activity of the GUS enzyme itself. The claims do not indicate that the coding sequence of interest encodes GUS, and the specification nor the prior art teaches that histone deacetylases reduce the activity of any and all enzymes. There is no evidence at all in the specification, or the prior art, that histone deacetylases act by repressing translation, or by repressing any level of gene expression other than transcription. Further, Applicants' own publication, presenting the identification and characterization of AtHD2A and AtHD2B, even teaches that histone deacetylases are enzymes that remove acetyl groups from the core histones and repress gene transcription (Wu et al., Plant J., 2000, Vol. 22, pages 19-27, see abstract, pages 19, 20, 23, 24). Applicants also argue that page 15 of the specification states that repression of gene expression may involve reducing levels of mRNA, protein, or both (response, paragraph briding pages 6-7). However, this passage only indicates what is intended to be encompassed by the recitation, "repression of gene expression activity." See also Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure".

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and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Further, the specification does not teach that the amino acid residues encoded by nucleotides 61-855 and 61-655 of SEQ ID NO: 7 retain the transcription-repressing activity of SEQ ID NO: 8. As discussed above, Applicants argue that these nucleotides are inferred from the specification and drawings. However, for the reasons outlined above, and given that SEQ ID NO: 8 has 60 more amino acids than SEQ ID NO: 6, further guidance would have been required by one skilled in the art to determine the nucleotide sequences of SEQ ID NO: 7 that correspond to the sequences of SEQ ID NO: 5 that encode the catalytic residues and acidic domain of SEQ ID NO: 6. One skilled in the art could not have inferred from the specification as filed that, for example, the acidic domain of AtHD2B contains 18 more amino acids than the acidic domain of AtHD2A.

11. Claims 42-49 and 51-53 are objected to. Claims 1-3, 5-9, 11-19, and 32-41 are rejected. Claim 31 is allowed.

### **Contact Information**

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this

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application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

June 30, 2003

ASHWIN D. MEHTA, PH.D. PATENT EXAMINET

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